

**REMARKS**

This Amendment is submitted in response to an Office Action mailed on April 14, 2003, and also in connection with a Request for Continued Examination (RCE) filed concurrently herewith. By this amendment, claims 1, 27 and 51 have been amended.

In the Office Action, the Examiner made a final rejection of claims 1-7, 17-18, 26-32, 41-42, 50-55, 61, 64-65 and 73 under 35 U.S.C. §103(a) as being unpatentable over Japanese Patent No. 2000-37456 to Gaisha et al. in view of U.S. Patent No. 5,141,496 to Dalto et al. Applicants respectfully traverse that rejection.

As noted by the Examiner, Gaisha et al. fails to teach or suggest a limiter including a generally flat skin engaging surface. The Examiner has taken the position that Dalto et al. overcomes that deficiency. Dalto et al. discloses a spring impelled syringe that controls the penetration depth of a needle tip during injection. Initially, (i.e., prior to use), the syringe 2 and needle 11 are contained within a fixed body 4, including its frustoconical base 1. In use, the base 1 is placed against the skin of a patient, and the syringe 2 and needle 11 are caused to move by a spring 9 until the needle penetrates the patient's skin to the desired depth. The drug substance may then be expelled from the syringe by depression of the plunger rod. Notably, the syringe 2 and needle 11 are not fixed in place with respect to the base 1.

In contrast, applicants' invention recites that the limiter portion and needle cannula are non-movable with respect to each other. That is neither taught nor suggested by Gaisha et al. or Dalto et al., whether considered alone or in combination, as suggested by the Examiner, or whether considered in combination with any other prior art reference in the present application,

or with the knowledge of a person of ordinary skill in the art. Thus, applicants respectfully submit that their invention, as recited by the claims as amended herein, is patentable over the prior art references of record. Applicants further respectfully submit that the Examiner's rejection of claims 1-7, 17-18, 26-32, 41-42, 50-55, 61, 64-65 and 73 as unpatentable under 35 U.S.C. §103(a) is no longer tenable, and respectfully request withdrawal of that rejection.

The Examiner has also rejected claims 8-9, 33-34, 56-57 and 62-63 under 35 U.S.C. §103(a) as being unpatentable over Gaisha et al. in view of Dalto et al., and further in view of U.S. Patent No. 5,147,328 to Dragosits et al. Applicants respectfully submit that the disclosure of Dragosits et al. does not overcome the deficiencies noted above with respect to Gaisha et al. and Dalto et al. In view of the distinguishing remarks set forth above with regard to Gaisha et al. and Dalto et al., applicants respectfully submit that the Examiner's rejection of claims 8-9, 33-34, 56-57 and 62-63 under 35 U.S.C. §103(a) is no longer tenable, and respectfully request withdrawal of that rejection.

The Examiner has also rejected claims 24-25, 48-49 and 71-72 under 35 U.S.C. §103(a) as being unpatentable over Gaisha et al. in view of Dalto et al., and further in view of U.S. Patent No. 5,672,883 to Reich. Applicants respectfully submit that the disclosure of Reich does not overcome the deficiencies noted above with respect to Gaisha et al. and Dalto et al. In view of the distinguishing remarks set forth above with regard to Gaisha et al. and Dalto et al., applicants respectfully submit that the Examiner's rejection of claims 24-25, 48-49 and 71-72 under 35 U.S.C. §103(a) is no longer tenable, and respectfully request withdrawal of that rejection.

Finally, applicants respectfully submit that all claims pending in the present application, i.e., claims 1-7, 17-18, 24-35, 41-42, 48-58, 61-65 and 71-73, are now in condition for allowance and request prompt allowance thereof.

Applicant hereby authorizes the Commissioner to charge the fees necessary in connection with this Amendment and any other fees necessary in connection with this application, to Deposit Account Number 02-1666.

Any questions concerning this application or amendment may be directed to the undersigned agent of applicant.

Respectfully submitted,

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By: David Fortunato  
David M. Fortunato  
Attorney for Applicant(s)  
Reg. No. 42,548  
(201) 847-6940